Treating and Preventing HIV in Diverse Communities

A New Era of HIV Prevention

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Outline

• Urgency of HIV prevention
• The prevention toolkit
• HIV prevention
  • Past
  • Present
  • Future
• Questions / Discussion
Rates of Diagnoses of HIV Infection among Adults and Adolescents, by Race/Ethnicity
2010–2014—United States

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

*Hispanics/Latinos can be of any race.
Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting. a Hispanics/Latinos can be of any race.
Lifetime Risk of HIV Diagnosis among MSM by Race/Ethnicity

- African American MSM: 1 in 2
- Hispanic MSM: 1 in 4
- White MSM: 1 in 11

Source: Centers for Disease Control and Prevention
HIV prevention
Past
Present
Future
HIV prevention
Past

Condoms
Abstinence

Structural interventions
HIV prevention
Present

~Adherence behavior
~Structural interventions to ensure appropriate care and services
Perinatal prophylaxis to prevent maternal to child transmission of HIV

ACTG 076 Connor et al, 1994, NEJM

Occupational post-exposure prophylaxis (PEP)

Non-occupational PEP (nPEP)
Prevention of HIV-1 Infection with Early Antiretroviral Therapy


ABSTRACT

BACKGROUND

Antiretroviral therapy that reduces viral replication could limit the transmission of human immunodeficiency virus type 1 (HIV-1) in serodiscordant couples.

METHODS

In nine countries, we enrolled 1723 couples in which one partner was HIV-1-positive and the other was HIV-1-negative. 44% of the subjects were from Africa, and 56%

*The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Cohen at the University of North Carolina at Chapel Hill, Institute for Global Health and Infectious Diseases, Suite 251C, Bioinformatics Bldg., 305 Manning Rd., CB 5306, Chapel Hill, NC 27599, or to hpto52@unc.edu.
FDA approval of Truvada as PrEP, 2012
Clinical Trial Evidence for HIV Prevention Options (February 2016)

Prevention of sexual transmission:
- PROUD — daily oral TDF/FTC
- IPERGAT — event-driven TDF/FTC
- Partners PrEP — daily oral TDF/FTC (KwaZulu-Natal, South Africa)
- Partners PrEP — daily oral TDF
- TFPR — daily TDF/FTC
- BRIA — daily oral TDF/FTC

Effect size (CI):
- 80% (58, 97)
- 80% (44, 99)
- 75% (55, 87)
- 63% (44, 81)
- 62% (37, 84)
- 44% (15, 63)
- 39% (8, 62)
- 31% (1, 51)
- 31% (1, 51)
- 27% (1, 46)
- 19% (1, 39)
- 8% (1, 14)
- 6% (1, 14)
- 4% (1, 14)

Prevention in people who need drugs:
- START + TDF
- START + TDF
- START + TDF
- START + TDF
- START + TDF

Adapted from: Salim S. Abdool Karim, CAPRESA
### PrEP guidelines

#### Summary of Guidance for PrEP Use

<table>
<thead>
<tr>
<th>Substantial Risk of Acquiring HIV</th>
<th>Men Who Have Sex with Men</th>
<th>Heterosexual Women and Men</th>
<th>Injection Drug Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-positive sexual partner</td>
<td>HIV-positive sexual partner</td>
<td>HIV-positive sexual partner</td>
<td>HIV-positive injecting partner</td>
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<tr>
<td>Recent bacterial STI</td>
<td>Recent bacterial STI</td>
<td>Recent bacterial STI</td>
<td>Sharing injection equipment</td>
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<tr>
<td>High number of sex partners</td>
<td>High number of sex partners</td>
<td>History of inconsistent or no condom use</td>
<td>Recent drug treatment (but currently injecting)</td>
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<td>History of inconsistent or no condom use</td>
<td>Commercial sex work</td>
<td>Commercial sex work</td>
<td></td>
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<tr>
<td>Commercial sex work</td>
<td>In high-prevalence area or network</td>
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<tr>
<td><strong>Eligible</strong></td>
<td>Documented negative HIV test result before prescribing PrEP</td>
<td>Documented negative HIV test result before prescribing PrEP</td>
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<td></td>
<td>No signs/symptoms of acute HIV infection</td>
<td>No signs/symptoms of acute HIV infection</td>
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<tr>
<td></td>
<td>Normal renal function, no contraindicated medications</td>
<td>Normal renal function, no contraindicated medications</td>
<td></td>
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<tr>
<td></td>
<td>Documented hepatitis B virus infection and vaccination status</td>
<td>Documented hepatitis B virus infection and vaccination status</td>
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<tr>
<td><strong>Administration</strong></td>
<td>Daily, continuing oral doses of TDF/FTC (Truvada), 90-day supply</td>
<td>Daily, continuing oral doses of TDF/FTC (Truvada), 90-day supply</td>
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<tr>
<td><strong>Adherence</strong></td>
<td>Follow-up visits at least every 3 months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment</td>
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<tr>
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<td>At 3 months and every 6 months thereafter, assess renal function</td>
<td>At 3 months and every 6 months thereafter, assess renal function</td>
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<tr>
<td></td>
<td>Every 6 months, test for bacterial STIs</td>
<td>Every 6 months, test for bacterial STIs</td>
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<tr>
<td></td>
<td>Do oral/rectal STI testing</td>
<td>Do oral/rectal STI testing</td>
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<tr>
<td></td>
<td>Assess pregnancy intent</td>
<td>Assess pregnancy intent</td>
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<tr>
<td></td>
<td>Access to clean needles/syringes and</td>
<td>Access to clean needles/syringes and</td>
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[www.CDC.gov](http://www.CDC.gov)
Barriers to prescribing

Who is prescribing
- Specialty vs. primary care providers
- Cultural competency
- Talking about sex

Clinical concerns
- Unfamiliarity in prescribing antiretrovirals
- HIV and STI testing; safety monitoring; extra visits
- Lack of routinely provided adherence support
- Combination prevention methods still required

Payment and logistics
- Payment for PrEP (expensive) and concerns about payment
- Insurance disclosures (minors)
- Paperwork
### Interventions to Enhance PrEP Uptake

- Mass media campaigns
- Community mobilization
- Alternative PrEP formulations
- Community-based efforts to de-stigmatize PrEP

- Medication and/or co-payment waivers
- Free service provision
- Enhanced access
  - Centralized provision
  - Enhanced referral systems

- Provider education/training
- Electronic tools to assess sexual risk and indicate PrEP
- Automated systems to minimize provider burden

- Counseling
  - Medication adherence
  - Sexual risk reduction
  - Home support systems to minimize patient testing burden
  - Electronic adherence
Adherence support as well as innovative delivery methods are key

Trials of oral and topical tenofovir-based PrEP show that these strategies reduce risk of HIV infection if they are used correctly and consistently. Higher adherence is directly linked to greater levels of protection.

Calculations based on analyses involving a subset of total trial participants.

www.avac.org
Many resources available

• Federal agencies
  • www.CDC.gov
  • www.AIDS.gov
  • Medicaid

• Multiple organizations
  • Local Departments of Health, clinics, CBOs
  • www.nastad.org
  • www.ProjectInform.org
  • Private healthcare innsurers

• Pharmaceutical company (www.Gilead.com)
Where we once only had condoms…

HIV prevention

Future
Dapivirine ring, 2016

Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women


ABSTRACT

Two large clinical trials—The Ring Study and ASPHE—have shown that a monthly vaginal ring containing the antiretroviral drug dapivirine can prevent HIV in women and is safe for long-term use. Developed by NNRTI over the past 10 years, the drug reduces infections by approximately 50 percent overall in the “after” studies, with differences in efficacy seen by age. Notably, a vaginal ring was used toward higher efficacy, with more consistent ring use.

This is the first time that the Phase II studies have confirmed statistically significant efficacy for a microbicide to prevent HIV. As the first long-acting HIV-prevention method, the dapivirine ring could be an important new option for women, who bear the greatest burden of the global epidemic. It also provides regulatory approval for the ring to be tested for efficacy in the Product Development Partnership Project (PDP) trials.

Learn more about the results from the Phase II dapivirine ring studies.

* HIV press release: Two Large Studies Show Monthly Vaginal Ring Prevents HIV

[Link to press release: HIV press release: Two Large Studies Show Monthly Vaginal Ring Prevents HIV]
HIV prevention
And more

• Long acting PrEP agent GSK744LA (cabotegravir) safe and well tolerated among low to moderate risk MSM
  • Éclair
• TAF showing promise as oral PrEP
• Maraviroc alone and in combination is safe and well tolerated among MSM and transgender women
  • HPTN 069
• Bone mineral density regroups after stopping Truvada
Broadly neutralizing monoclonal antibodies

This antibody is a broadly neutralizing antibody to HIV. Its name is VRC01. It stops HIV from binding to human T-cells by attaching to the virus and preventing it from infecting the T-cell.

(1) The VRC01 antibody is able to bind onto HIV at the (2) CD4 binding site on the gp120 protein. (3) This neutralizes HIV and prevents HIV from being able to attach to cells and infect them.

www.ampstudy.org
We still need to overcome barriers to HIV prevention services and utilization

Racism
Poverty
Homophobia
misogyny
conventionalism
SHAME
violence
STIGMA
marginalization
homelessness
CLASSISM

BAR BEFORE THE BARS  DIAGNOSED  LINKED TO CARE  RETAINED IN CARE  PRESCRIBED ART  VIRALLY SUPPRESSED

www.nastad.org
HIV Prevention

- Vaccines
- Male and female condoms
- PrEP
- Microbicides
- Cervical barriers: vaginal diaphragms
- Clean injecting equipment
- Voluntary counselling and testing
- PMTCT
- Male circumcision

bNABS
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- Participants and colleagues in DMV community

- Several images from slides from
  - The AMP study
  - NASTAD
  - AVAC
  - Be the Generation
  - CROI
Thank you!

Questions?